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UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

In the Matter of)	
)	Docket No. FIFRA-92-H-04
Metrex Research Corporation,)	
)	
Respondent.)	

ORDER ON DISCOVERY

Metrex's motion to depose Dr. Virginia Chamberlain, Mr. Tim Ulatowski and Dr. Chiu Lin, is denied.

Dr. Chamberlain is not listed as a witness by the EPA but her deposition is sought on the grounds that she is the official in charge of FDA germicide enforcement and can provide information on the division of regulatory authority between the EPA and the FDA as set out in Memorandum of Understanding between the EPA and the FDA executed in June 1993 ("MOU"). That document gave the FDA primary responsibility for the premarket review of safety and efficacy for liquid chemical germicides that are sterilants intended for use on critical or semicritical devices. The MOU was designed to eliminate the duplicative regulation of certain liquid chemical germicides in areas where the two agencies have overlapping jurisdiction.¹ Primary responsibility for the premarket review of the safety and efficacy of liquid chemical germicides that are sterilants was

¹ The MOU is attached as Exhibit A to Metrex's motion.

assigned to the FDA because it was recognized that premarket clearance by the FDA would also fulfil certain EPA registration requirements with respect to efficacy and product performance.

The language in the MOU speaks for itself and I find that it is not material to the issues of this case to probe behind it.

Mr. Ulatowski and Dr. Lin are also not listed as witnesses by the EPA and their depositions are sought on the ground that they are knowledgeable about the testing being done by the FDA on the efficacy of products such as those at issue here.

Metrex has identified its own experts with respect to the validity of the testing relied upon by the EPA. It has not been shown that Mr. Ulatowski and Dr. Lin are likely to produce evidence of significant probative value on that issue over and above the evidence Metrex can produce through its own witnesses or which otherwise may be available to it.

Metrex's depositions of Dr. Syed A. Sattar and Ms. Susan Springthorpe are also denied.

The depositions of these individuals are sought because they are said to be conducting research and development on the sporicidal test method which the EPA requested and which is expected to either improve the AOAC method or develop a new test method.² These witnesses have also not been listed as EPA witnesses in the EPA's prehearing exchange.

Evidence that the EPA has been studying the AOAC Sporicide

² See 55 Fed. Reg. 50388 (Dec 6, 1990) for the EPA's request for proposals for the research, attached as Exhibit B to Metrex's motion.

Test method with a view to improving it is of doubtful materiality. Presumably, if the EPA finds a better or more reliable method for testing these products it will adopt it. It is not the function of this proceeding to determine whether there is a more reliable or better test method but whether the testing that was done in this proceeding, whatever its alleged defects, was sufficiently reliable to support the EPA's claim of lack of efficacy.³

Metrex's request to depose James Cholinsky, James Danielson, Juan Negrón, Everett Greer and Dallas P. Wright is granted. These individuals are described as persons who did the actual testing or were responsible for quality control of the testing. Mr. Cholinsky and Mr. Negrón have been listed as witnesses for the EPA.

The validity of the tests relied upon by the EPA is a material issue in this case. The issue can be highly technical and the depositions may serve to simplify or clarify the issue or possibly

³ The EPA argues that the reliability of the AOAC test method is not a proper issue in this proceeding but should have been raised on promulgation of the regulation adopting the test (40 C.F.R. 158.108 referencing Pesticide Administrative Guidelines, Subdivision G - Product Performance). The argument raises questions as to the ripeness of review of the issue at that time, Cf. Abbot Laboratories v. Gardiner, 387 U.S. 136 (1967), as well as whether such review was entitled to any preclusive effect. The argument at this point is not convincing. Evidence tending to show that the AOAC test method used to test the products at issue here has the inherent nature to produce "false positives" is relevant to the reliability of the test and as such appropriately considered in this proceeding. I also do not regard Metrex's attack on the AOAC test as inconsistent with the fact that Metrex relied on such test to support the registration of its products. Evidence that the test method produces inconsistent results is also relevant to the reliability of the tests. The question still remains, of course, whether notwithstanding such defects, if they exist, the tests are sufficiently reliable to sustain the EPA's claims of the lack of efficacy.

even lead to settlement.

The EPA argues that this evidence can be obtained by Metrex's proposed depositions in the United States District Court. We do not have the schedule for those depositions. Indeed, it appears that no time has yet been set. In any event, what is important is that the depositions be taken in time to be of use in this proceeding, and ordering them here will ensure that this is done.⁴

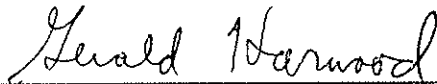
The depositions herein ordered shall be taken in the city where the persons work or live and at the times specified by Metrex or at such other time as may be mutually agreed to and will not delay the hearing.

The deposition of Elizabeth Crowley is denied. Her deposition is sought so that Metrex can learn the basis for the proposed penalty. Metrex will have an opportunity to cross-examine Ms. Crowley when she appears as a witness for the EPA, and it has not been shown why this will not be adequate, since the FIFRA Enforcement Response Policy is available to it. The ultimate question as to the appropriateness of the penalty will, of course, be determined on the basis of the facts as developed in the hearing.

The EPA's request for discovery is denied. That appears to be

⁴ It is assumed that my order granting these depositions will be honored by the EPA without the necessity of issuing a subpoena, even though Mr. Cholinsky and Mr. Danielson appear to be FDA employees who did the testing for the EPA. If this is not the case, I question whether there is authority to issue a subpoena in proceedings under FIFRA, section 14(a), 7 U.S.C. 1361(a). If there is a problem of compliance with the depositions, Metrex may apply for such appropriate relief as is within my authority to grant.

an omnibus request for Metrex's documents and records relating to the shipment and sale of the products at issue. The request is conditioned upon my granting discovery to Metrex. The connection between Metrex's request and the documents and records the EPA seeks is not clear. It would appear, then, that the documents and records are not of great probative value. Presumably most or all of this information could have been obtained in the course of the EPA's investigation. Consequently, the request is denied.



Gerald Harwood
Senior Administrative Law Judge

Dated: August 26, 1993

CERTIFICATE OF SERVICE


I do hereby certify that the foregoing Order on Discovery was filed in re Metrex Research Corporation; Docket No. FIFRA 92-H-04 and a copy of the same was mailed to the following:

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Dated: August 26, 1993